REMARKS

Claim Status

Claims 1, 4-7, 20-22, 26, 27, 57 and 57-60 are pending in the present application. No additional claims fee is believed to be due. Claims 2-3, 8-19, 23-25, 28-53 and 55-56 are canceled without prejudice.

Rejection Under 35 USC §103(a) Over Diehl (EP0505374B1) of record and Tulin-Silver (US 5,508,282) in view of Makino et al. (US 4789667) of record and in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927), of record and in further view of "Dissociation Constants of Organic Acids and Bases", in CRC Handbook of Chemistry and Physics, Version 1996 (77th ed) David R. Lide, ed., pp. 3-15 and 3-173) of record

Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 have been rejected under 35 USC §103(a) as being unpatentable over Diehl (EP0505374B1) of record and Tulin-Silver (US 5,508,282) in view of Makino et al. (US 4789667) of record and in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927), or record and in further view of "Dissociation Constants of Organic Acids and Bases", in CRC Handbook of Chemistry and Physics, Version 1996 (77th ed) David R. Lide, ed., pp. 3-15 and 3-173) of record. The Examiner states that Deihl discloses a pharmacological composition for the treatment of the common cold by spraying said composition into the oral cavity. The composition comprises vitamin C and a non-toxic zinc salt. The Examiner states that Tulin-Silver discloses a composition comprising Vitamin C from about 15mg to about 300 mg and zinc in the amount of 0.50mg. Further the Examiner states that Tulin-Silver discloses that the composition is for the treatment of relieving and shortening the duration of inflamed nasal memebrane turbinates; nasal congestion; acute upper respiratory

infections and that the Tulin-Silver's pilot study demonstrated that the nasal Spray formulation shortened the duration of the common cold symptoms. The Examiner states that Makino discloses a pharmaceutical composition for external use with enhanced pharmacologically active agent through the skin and that the composition comprises a pharmacologically active agent and an optically active or inactive pyroglutamic acid ester. The Examiner then states that Kuhrt discloses that Rhinovirus as a group is notably sensitive to inactivation in solutions with a pH of less than 5.3. Appellants respectfully traverse this rejection based on the remarks contained herein.

"The citing reference that merely indicate[s] that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." See Ex parte Hiyamizu, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). There should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention. Note In re Dembiczak 175 F. 3d 994, 999 (Fed. Cir. 1999). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be **important** to identify **a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way claimed new invention does. This is so because **inventions in most, if not all, instances rely upon building blocks since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.**" KSR, 1727 S. Ct. 1727, at 1741 (2007) (emphasis added). A quote acknowledging a "helpful insight" by the Court of Customs and Patent Appeals when that court first established TSM. "Often, it will be necessary for a court to look to interrelated teachings of multiple patents; . . . **to determine whether there was an apparent reason** to combine the known elements in the fashion claimed by the patent at issue." KSR, 1727 S. Ct. at 1740-41 (emphasis added).

Deihl discloses a composition that provides vitamin C in the manufacture of a pharmacological composition that can be used to treat common colds. Diehl does not

teach or suggest a method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and from about 0.01% to about 10% organic acid organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Deihl specifically excludes nasal administration by calling out that the invention "is concerned with treatment of the common cold by spraying a pharmacological composition into the oral cavity" See Page 2, lines 24-28. Example V specifies that the compositions are sprayed " every two hours during wakeful periods into the mouths of patients" Additionally, Deihl never teaches or suggest a pH or that the pH of the nasal tissue when the solution is delivered to the nasal tissue is 3.5 to about 5.5 on the nasal tissue or a dissociation constant (pKa) value from about 3.0 to about 5.0. The Examiner relies on the "Dissociation Constants of Organic Acids and Bases, in CRC Handbook of Chemistry and Physics, Internet Version 2007(87th Edition), to provide support for the inherency of the compounds properties, however, the Examiner cannot rely on this reference, since the current application has a file date of October 19, 2000. Additionally, Deihl never teaches or suggest that the pharmacological composition comprise a pH adjusting agent or pyroglutamic acid.

Tulin-Silver discloses a nasal spray containing ascorbic acid and caffeine in thearapuetically effective amounts at a pH from 5.5 to 6.5 provide benefits in treating acute and chronic rhinosinusitis. Tulin-Silver does not teach or suggest a method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and ~~an~~ from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Tulin-Silver discloses that the combination of ascorbic acid by itself, caffeine by itself and the combination of ascorbic acid caffeine at the desired pH maybe effective. In the pilot one

subject found that the combination of ascorbic acid and caffeine to not even be effective. Additionally, all of the pilot study formulations were at a pH of 5.5 or greater.
tissues.

Makino discloses a pharmaceutical composition for external use that provides for enhanced penetration or permeation of drugs. Makino discloses that pyroglutamic acids can be used to aid in penetration of the drug through the external topical skin or mucosa of a warm blooded animal. Makino fails to teach or suggest a method for treating the cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and ~~an~~ from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

The present invention utilizes pyroglutamic acid in combination with organic acids to create a hostile environment on the surface of the nasal cavity not for the delivery of drug that penetrate a mucosa. The Examiner's suggested modification would render the prior art unsatisfactory for its intended purpose. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

Kuhrt discloses a study to determine if the virucidal activity of glutaric acid is solely due to low pH of a solution in which it is tested or to the intrinsic property of the chemical entity. Kuhrt discloses in the summary of the test that glutaric acid appears to inactive RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures and that the aciduant effect at room temperature is not detectable. (See page 927, last paragraph). Kuhrt does not teach or suggest a method a treating the common cold with a composition that comprises pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a

homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Kuhrt does not teach or suggest a homogeneous solution that has a pH of 3.5 to about 5.5 on the nasal tissue.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Deihl, Tulin-Silver, Maniko et al. and Kuhrt et al., one would still fall short of the of Appellants' claimed invention only to arrive at a composition for the mouth or nasal passage that comprises vitamin C, caffeine, glutaric acid and zinc that utilizes pyroglutamic acid to enhance drug delivery and inactivates RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures.

The combination of Deihl, Tulin-Silver, Maniko et al. and Kuhrt et al., do not teach or suggest each and every element of Appellants' presently claimed invention i.e. A method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and ~~an~~ from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

Accordingly, Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are novel over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully Submitted,

THE PROCTER & GAMBLE COMPANY

By /Cynthia L. Clay/
Cynthia L. Clay
Registration No. 54,930
(513) 622-0291

March 5, 2010

Customer No. 27752